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Remarks

Upon entry of the present amendment, claims 41-43 and 45-58 are pending in the application,

with claims 41 and 58 being the independent claims. Claim 44 has been canceled. Claims 43 and

45-47 have been amended to remove the word "and", and to depend on claim 41, respectively.

Support for the amendment to claims 41 and 58 may be found, for example, in original claim 44 and

in the specification at page 78, lines 17-20. No new matter is added by way of these amendments,

and their entry is respectfully requested. Further, since the amendment to claims 41 and 58 merely

incorporates the language of previously pending claim 44 into the claims, the amendment does not

require a new search or consideration. It is submitted that the amendment places the claims in

condition for allowance, or in better condition for appeal. For these reasons, entry of the

amendments is respectfully requested.

Applicants respectfully request that the Examiner consider the above amendments and the

following remarks, and withdraw the outstanding rejections.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 41-58 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventors, at the time the application was filed, had possession of

the claimed invention. The rejection is traversed.

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The Office Action contends that the present specification only describes an isolated

expression vector comprising SEQ ID NO: 1 linked 5' to a start codon of yeast open reading frames

(ORFs), and fails to provide written description of representative nucleic acid molecules from other

classes of organisms encompassed by the generic claims.

Applicants respectfully traverse the rejection, and reiterate the arguments made in their

response filed October 6, 2004. The specification describes the use of 5'-CACC primers to make

expression constructs that exhibit enhanced the translational efficiency of the cloned ORF:

"The primers employed in the amplification step are specific for each desired gene

sequence and include a variety of unique features. For example, the 5' "sense"

primer starts with the sequence 5'-CACCATG... (the start codon is underlined). The CACC sequence is added as a Kozak consensus that aids in translational efficiency."

(Specification at page 4, lines 9-12). Thus, the linkage of 5'-CACC immediately 5' to a start codon

of an ORF is described in the context of ORFs from any organism. The specification at page 4,

lines 9-17, clearly describes the linkage of 5'-CACC sequences immediately 5' of a start codon of an

ORF, wherein the ORF is fused in-frame with a heterologous peptide such as an epitope tag or

affinity purification tag, again in the context of ORFs from any organism. Example 1 of the

specification teaches the use of 5'-CACC primers to make expression vectors containing 5'-CACC-

linked yeast ORFs; and Example 2 teaches the use of "...specific primer sets, essentially as

described above..." (i.e., 5'-CACC primers as in Example 1) to make expression vectors containing

5'-CACC-linked human ORFS. Table 2 provides a large list of human ORFs to which the 5'-CACC

sequence may be linked. Given the level of knowledge readily available in the art, and the teachings

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provided in the present specification, those skilled in the art would have understood that Applicants

were in possession of the claimed invention when the application was filed.

The specification is fully compliant with the written description requirement of 35 U.S.C.

§ 112, first paragraph, and Applicants therefore respectfully request that the rejection be

reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 102(e)

Claims 41-58 were rejected under 35 U.S.C. § 102(e) as being anticipated by Dubensky, Jr.

et al. (U.S. Patent No. 6,342,372). Claim 44 has been canceled. Thus, the rejection as it applies to

this claim is moot. Applicants respectfully traverse the rejection as it applies to claims 41-43 and

45-58.

The '372 patent fails to disclose "an isolated expression vector, comprising the sequence

5'-CACC linked immediately 5' to a start codon of an open reading frame (ORF), wherein the

ORF is linked in-frame to a polynucleotide encoding a heterologous peptide, thereby encoding a

fusion protein comprising a polypeptide encoded by the ORF and the heterologous peptide" as

presently claimed. The Examiner cites column 157, line 67 to column 158, line 5 of the '372

patent as disclosing this feature. Column 157, line 67 to column 158, line 5 of the '372 patent

states:

"Preferred methods of purification includes various cell sorting techniques, such as antibody panning, FACS, and affinity chromatography using a matrix coupled to antibodies specifically reactive to the desired cell type(s). Isolated cells are then transduced, after which they may be immediately re-introduced to the patient from which

they were withdrawn."

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This section of the '372 simply is not relevant to the pending claims: it discusses methods of cell purification using cell-type specific antibodies, and does not even hint at fusion proteins. Since the '372 patent does not disclose all of the elements recited in claims 41 and 58, it cannot anticipate the present claims. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) therefore is respectfully requested.

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Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

Date: <u>April 27, 2005</u>

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